

BQC - 88 - 048

Date: November 4, 1988

To: All Wisconsin Hospitals

From: Larry Tainter, Director
Bureau of Quality Compliance

Subject: New Federal Condition of Participation for Hospitals Requirement for Protocols to Identify Potential Organ Donors

Effective March 31, 1988, all general hospitals participating in the Medicare/Medicaid hospital certification programs were to be in compliance with a new federal condition of participation for hospitals.

The purpose of this memo is to remind you of the requirement, and to inform you of the procedure that the Department has developed to verify compliance with the requirement. The new requirement is located in 42 CFR 481.12 Condition of Participation:

Governing body.

- (c) Standard: Care of patients. In accordance with hospital policy, the governing body must ensure that the following requirements are met: . . .
 - (5)(i) To identify potential organ donors as defined in 485.302 of this chapter, the hospital has written protocols that
 - (A) Assure that the family of each potential organ donor knows of its option either to donate organs or tissues or to decline to donate;
 - (B) Encourage discretion and sensitivity with respect to the circumstances, views and beliefs of the families of potential donors;
 - (C) Require that an organ procurement organization designated by the Secretary under 485.308 of this chapter be notified of potential organ donors.
 - (ii) In the case of a hospital in which organ transplants are performed, the hospital must be a member of the Organ Procurement and Transplantation Network established under section 372 of the Public Health Service Act and abide by its rules and requirements.
 - (iii) For purposes of this subparagraph, the term "organ" means a human kidney, liver, heart, lung, and pancreas."

All hospitals which participate in the Medicare/Medicaid programs are subject to the requirement of this Condition of Participation. Hospitals which have deemed status in the above programs through accreditation by the Joint Commission on Accreditation of Healthcare Organizations or the American Osteopathic Association are also subject to these requirements.

Specialty hospitals which provide care exclusively to psychiatric patients are exempt from these requirements. Also, general hospitals which may lack operating room facilities, equipment, and personnel to retrieve organs will be considered for exemption.

General hospitals, to whom the above requirements are applicable and who do not have effective protocols in place, will be subject to decertification under the rules of the Medicare/Medicaid programs.

It is important to note that Wisconsin state statutes do have a similar requirement located in ss.157.06(2m).

“Hospital Policy. (a) Each hospital shall have a policy based on accepted medical standards that requires, except as provided in par. (b), when a patient who is a suitable candidate, for the first of all or part of his or her body dies in the hospital, that the persons specified in sub. (2)(b) in the order and according to the procedure stated in sub. (2)(b) be requested to consider consenting to the gift of all or any part of the decedent’s body, which has not already been given under sub. (2), for the purposes specified in sub. (3).”

Hospitals already in compliance with Chapter 157 (attachment) should be able to achieve compliance with the new federal condition of participation with relative ease.

As previously noted, the federal Condition of Participation requires that the protocol, established to identify potential organ donors, must require that an organ procurement organization, designated by the Secretary of Health and Human Services under 1138(b)(1)(f), be notified of potential donors. The Department of Health and Human Services is recommending that an organ procurement organization assist with the development of hospitals’ written protocols for identifying potential donors.

The federally designated organ procurement organizations (OPO) for Wisconsin are the University of Wisconsin Hospitals and Clinics, Madison, and Froedtert Memorial Lutheran Hospital, Milwaukee. Attached are lists identifying the counties assigned to each of these organ procurement organizations. Please note that Douglas and St. Croix counties are not assigned to the Wisconsin OPOs. They are assigned to the Upper Midwest Organ Procurement Organization, Inc., located in Minneapolis, Minnesota.

Additional facts to consider include the following:

1. A hospital may have a relationship with any designated organ procurement organization. The hospital is not limited to the organ procurement organization designated for the area in which it is located.
2. Hospitals that perform organ transplants and participate in the Medicare/Medicaid programs must be a member of the United Network for Organ Sharing.
3. When Medicaid payment is involved, the organs must be procured in-house or through a designated organ procurement agency to ensure the Medicaid payment for the transplant.
4. With regard to tissue donation, a hospital needs only to make families aware of their option to donate tissue.

Since the Bureau of Quality Compliance is responsible for the enforcement of Conditions of Participation for Medicare and Medicaid certified hospitals, it is necessary that hospitals submit copies of their protocols for identifying potential donors to the Bureau of Quality Compliance by March 1, 1989. Hospitals that treat

psychiatric patients, only, are exempt from this requirement. General hospitals may request exemption from these requirements by submitting documentation supporting lack of adequate operating room facilities, equipment, and qualified personnel necessary to the successful retrieval of organs.

Please submit all above materials to:

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If you have any questions or comments, please contact Allan Stegemann at (608) 266-2055 or Phyllis Tschumper at (608) 266-0701.

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cc: Wisconsin Hospital Association
Wisconsin Medical Records Association
Wisconsin State Medical Society